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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,466	07/18/2003	Gary S. Dixon	976626-100/001	2973

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14252 CULVER DR. BOX 914
IRVINE, CA 92604

EXAMINER	
CHENG, JACQUELINE	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,466	DIXON ET AL.	
	Examiner	Art Unit	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments that the use of the combination of Faulkner (US 6,740,041), Pugh (US 4,631,676), and Lewandraowski (US 2002/0137082) is improper. The examiner does not agree with the applicant's belief that Faulkner merely instructs the use of demographic data. True, Faulkner discloses that demographic data such as age and gender of the patient can be used and inputted, but Faulkner also discloses the use of additional patient information such as patient's mobility (col. 3 line 20-35), which is associated with a patient's gait of how they can move. Although Faulkner does not explicitly disclose the use of bone maker information as additional patient information, Faulkner does disclose that the system accepts additional data, which is capable of being from another patient measurement system, such as the results from a bone maker examination (col. 1 line 65-67). Although Faulkner teaches that treating a patient can be done without requiring gait or bone marker information, he teaches that measurement of bone mineral density cannot alone provide an indication of absolute fracture risk, but are strongly dependent on factors independent of bone mineral density, which it is likely that other additional risk factors which are not mentioned in Faulkner will be discovered and therefore it would be obvious to one skilled in the art to use the most information in order to prescribe the best therapy (col. 1 line 53-64). Therefore the rejection as stated in the office action dated May 4, 2006, and repeated below, still stands.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 5-15, 23, 24, 35, 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,740,041 B2 (herein referred to as Faulkner et al) in further in view of US Patent No. 4,631,676 (herein referred to as Pugh) further in view of US Publication No. 2002/0137082 A1 (herein referred to as Lewandrowski et al.).

Claims 1, 5-14, 24, 35, 38-40: Faulkner et al. discloses a bone densitometer that accepts additional patient data to produce a more accurate output measurement of a person's risk of osteoporosis. Bone densitometers provide a measurement of a bone characteristic level such as the T-score of a bone mineral density. These measurements are typically taken with x-ray, ultrasound, or tomography (col. 1 line 6-50). The bone densitometer of Faulkner et al., takes into account the risk factors of a patient such as the age of the patient and the patient's history of fractures when determining the patients' risk of fracture. This information is inputted into a computer, which processes and displays the information (col. 2 line 66-col. 3 line 5).

Pugh discloses a video gait system that analyzes a patient's gait so that a therapy or correctable surgery can be suggest to prevent bone deterioration or disorders (col. 1 line 12-24).

Lewandrowski et al. discloses a method of detecting osteoporosis in which a sample of bone related tissues or cells, such as the urine, are used to determine the concentration of a biochemical marker. This biochemical marker concentration in conjunction with a bone mass

measurement maybe used to identify people with high bone turnover, or they can be used to identify subgroups of patients to determine which is the best type of therapy for them (abstract, paragraph 0026, paragraph 0035).

It would be obvious to one with ordinary skill in the art at the time of the invention to combine Faulkner et al., Pugh, and Lewandrowski et al. as all these methods are ways of determining the risk factor of a patient for osteoporosis. The results from the video gait system of Pugh and the results from the bone marker concentration of Lewandrowski et al. can be inputted into the system of Faulkner et al. Using this information the doctor can then determine the patient's risk factor of breaking a bone, or of osteoporosis, and the doctor can also prescribe the most proper therapy depending on the patient's result from the combined information.

Claim 15, 41: It is obvious to one with ordinary skill in the art at the time of the invention that to obtain information about a biochemical marker, such as deoxypyridinoline from a urine sample, which characterizes bone resorption (Lewandrowski et al., paragraph 0036), the body fluid must be put in a container to be analyzed and to obtain the bone marker level a output must be outputted. Since the result would be the same whether there is a mechanism for holding the container with the sample, or if the container of the sample itself was analyzed without the extra mechanism, the mechanism is not necessary.

Claim 23: Lewandrowski et al. discloses measuring the bone mass density from the spine, hip, wrist, hand, heel, or the entire body to evaluate density (paragraph 0028).

Claim 42: The system of Faulkner et al. already processes and calculates a bone risk fracture dependent upon multiple factors. It would be obvious to have the computer output a recommendation dependent upon the risk factor result.

4. **Claims 2-4, 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al. in view of Pugh in view of Lewandrowski et al. as applied to claim 1 and 35 above, and further in view of US Patent No. 6,234,969 B1 (herein referred to as Chaintreuil et al.). Chaintreuil et al. discloses a bone densitometer having a housing for a foot in which a pair of ultrasonic transducers engages the heel at a controlled pressure. The ultrasonic waves that are detected are the used to calculate an quantitative ultrasound index, or a stiffness value (fig. 1, col. 4 line 14-61). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Chaintreuil et al. with Faulkner et al, Pugh, and Lewandrowski et al. as the invention of Chaintreuil et al. is assessing bone characteristics, in helping to determine osteoporosis. Faulkner et al. also disclosed that typical bone densitometers include ultrasonic ones.

5. **Claims 16, 17 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al. in view of Pugh in view of Lewandrowski et al. as applied to claim 1 and 35 above, and further in view of US Patent No. 4,195,643 (herein referred to as Pratt). Pratt discloses an apparatus for characterizing gait of a subject. To measure and characterize the gait, a person stands on a dual force plate system, which determines the force exerted by the right foot and the left foot. These forces can be compared to determine a difference in the forces exerted by each foot, and determine balance forces of the subject (col. 5 line 61-col. 6 line 14, fig. 3). Balance forces of a subject can also be measured with one foot off the ground (col. 9 line 62-65). It would be obvious to one with ordinary skill in the art at the time of the invention to combine

Pratt with Faulkner et al, Pugh, and Lewandrowski et al. as Pugh discloses that analyzing gaits helps to detect the deterioration of bones.

6. **Claims 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al. in view of Pugh in view of Lewandrowski et al. as applied to claim 1 above, and further in view of US Patent No. 6,803,197 B1 (herein referred to as Uitterlinden et al.). Uitterlinden discloses therapy for treatment of osteoporosis can include monifications to lifestyle, regular exercise, hormone therapy, biosphosphonates, vitamin D and calcium supplements. Since these are well known in the art that it would be obvious that these therapies would be recommended for a patient. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Uitterlinden with Faulkner et al., Pugh, and Lewandrowski et al. as they are all about determining bone deterioration.

7. **Claims 21, 22, 25-32 and 43-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faulkner et al. in view of Pugh in view of Lewandrowski et al. as applied to claim 1 above, and further in view of US Patent No. 6,086,538 (herein referred to as Jorgensen et al.). Jorgensen et al. discloses a method of evaluating the status of bone tissue useful in the diagnosis of osteoporosis. In this method Jorgensen et al. also discloses that it is beneficial to generate a historical record of the changes in some property of the individual patient's bone and make a diagnosis on basis of historical trends. The time period and frequency in which the future measurements are taken are dependent upon what a doctor chooses and can be in any time period and any frequency and of whichever types of measurement the doctor wishes to follow. It could

also depend on the therapy the doctor prescribes. The future measurements could be used to monitor the progress of the therapy.

As for the order and the extent of the analysis of the measurements that are done, they result in the same end result of the characterization of risk factor. The order in which the tests are done would not make a difference. It would be obvious to one skilled in the art at the time of the invention to try to get the most accurate and through diagnosis in order to prescribe the most proper therapy and to take into account the results of previous measurements. Faulkner et al.'s invention most embodies this with the ability to input other results and factors of osteoporosis into the computer.

It would be obvious to one with ordinary skill in the art at the time of the invention to combine Jorgensen et al. with Faulkner et al., Pugh and Lewandrowski et al. as they are all trying to determine osteoporosis risk for a patient.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lang (US 2002/0177770 A1) and Liew (US 2004/0106868 A1).

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER